REMARKS:

Claims 1-3, 5, 13-15, 17, 19-23, 25 and 27-31 were rejected under 35 USC 103(a) as unpatentable over Ito in view of Khan and Vanderzanden.

The office action states 'in summary Ito teaches a recombinant VSV expressing Ebola glycoprotein. Kahn teaches a live replication-competent VSV expressing a major glycoprotein, and a method of replacing VSV glycoprotein with another viral glycoprotein. Vanderzanden teaches a method of preparing a vaccine expressing the Ebola surface glycoprotein and that glycoproteins are the most logical to use in a vaccine to induce antibodies and elicit an immune response.'

In response, please find enclosed herewith an affidavit from inventors Jones and Stroeher which discusses the prior art and provides additional information on the inventive process.

As discussed therein, it is noted that neither Ito nor Kahn teaches a particle in which 'only the VHF glycoprotein is expressed on the surface of the recombinant VSV particle'. Rather, both Ito and Kahn teach supplying VSV G in trans for particle formation. As discussed therein, these particles were therefore not live and not replication competent.

As discussed in greater detail in the affidavit and as discussed in previous responses, there was no teaching or suggestion in the art that (a) a foreign VHF glycoprotein could functionally replace VSV G completely and (b) that such a particle could be used safely as a vaccine.

For example, it was believed that such particles would assemble improperly because of the substitution of native VSV G with the VHF glycoprotein. It

was believed that such particles might not be infectious and therefore would not be replication competent.

Yet further, it was believed that the Ebola glycoprotein was the main determinant of vascular cell toxicity and vascular injury and directly contributed to hemorrhage during infection. In addition, US-CDC considered the Ebola glycoprotein so dangerous that it was on the select agent list. Finally, as discussed in the affidavit, when the inventors were developing the invention, they were required to do all work in a BSL-4 laboratory because of the concerns regarding the harmful side-effects.

Thus, the prior art teaches that VSV G must be supplied in order for proper particle formation to occur and that substitution of VSV G with Ebola glycoprotein would likely not produce a live replicating virus. It further teaches that the Ebola glycoprotein is a dangerous, harmful protein. Accordingly, one of skill in the art would conclude that replacing VSV G with Ebola glycoprotein would not produce a live, replication-competent virus as one would expect that the particles would be defective due to the substitution of a non-native protein critical for particle formation. Furthermore, one of skill in the art would have concluded that even if such a particle was capable of replication, that it was not suitable for use as a vaccine because of the concerns regarding the 'safety' of Ebola glycoprotein. That is, it was believed by many in the field that if such a particle was capable of replication, it would in fact pose a significant health hazard. As discussed in the affidavit and as discussed above, this is borne out by the fact that the inventors were required to carry out their initial research in a BSL-4 facility. As discussed in greater detail in the affidavit, there were also

concerns regarding whether or not the glycoprotein would even elicit an immune response.

Surprisingly, the inventors have discovered that the recombinant VSV particle which is free of VSV G and which expresses only Ebola glycoprotein (for example) on its surface is not only replication-competent, it can also be used as a safe and effective vaccine which induces protective immunity without side effects, contrary to the teachings and expectations of the prior art.

It is further noted that the corresponding European application has been allowed.

In view of the foregoing, further and more favorable consideration is respectfully requested.

Respectfully submitted

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PER: _____

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